Exhibit 2

VIRGINIA EVANS

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA; the States of CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, WISCONSIN; the DISTRICT OF COLUMBIA; the CITY OF CHICAGO, and the CITY OF NEW YORK, ex rel. OSWALD BILOTTA,	:	Case No. 11 Civ. 0071 (PGG)
Plaintiffs and Relator,	:	
v.	:	
NOVARTIS PHARMACEUTICALS CORPORATION,	:	
Defendant.	:	
UNITED STATES OF AMERICA,	:	
Plaintiff,	:	
v.	:	
NOVARTIS PHARMACEUTICALS CORP.,	:	
Defendant.	:	

VIDEOTAPED DEPOSITION OF VIRGINIA EVANS
New York, New York
January 23, 2018

Reported by:
KATHY S. KLEPFER, RMR, RPR, CRR, CLR
JOB NO. 136542

A. Yes. I have actually published through the American Bar Association Health Law Litigation and Risk Management section a brief article on physician credentialing and the risks that can occur when a physician enters into an agreement with -- with respect to his or her competency and/or other agreement and how that can affect his status under the National Provider Database.

Q. Okay. We've also put before you DX3, which is the expert report of Heidi Sorensen which was prepared in response to your report.

Do you see that?

A. I do.

Q. And have you reviewed that report?

A. I have.

Q. What did you do to prepare for today's deposition?

A. I reviewed the materials that Ms. Sorensen referenced in her report. I reviewed the materials that I referenced in my report. I read both of those reports. I went back and looked at the PhRMA Code and the HHS OIG Guidance for Pharmaceutical Manufacturers. I

also discussed my testimony with counsel, Ms. Jude.

Q. And when did you do that?

A. I discussed my testimony on Friday for about two hours, three hours, and then again yesterday from 1 till about 6, so about five hours.

Q. Okay. When you say the HHS OIG Guidance, are you referring to the 2003 guidance?

A. Yes, sir. Uh-huh.

Q. And I believe that's in front of you as Defendant's Exhibit 4; is that correct?

A. Yes.

Q. Why don't we open up your report, and to give you a preview of what we're going to do today, for most of the day we're just going to walk through your report, and I'm going to ask you questions. Okay?

A. Okay.

Q. And then when I'm done with that, I'll likely ask you questions about Ms. Sorensen's report. Okay?

A. (Witness nods.)

Q. On page 1 of your report, we'll start with the Introduction. You say that the U.S. Attorney's Office engaged you to perform a review of and offer an opinion on the effectiveness of NPC's compliance program with respect to certain promotional events.

Do you see that?

A. Yes, sir.

Q. What do you mean by "effectiveness"?

A. When I talk about effectiveness in the context of this report, I'm referring back to the concept of effectiveness as that is described in the Sentencing Guidelines and as is understood in the compliance industry, not only the Sentencing Guidelines, but also the OIG pharma compliance for -- excuse me, compliance guidance for pharma manufacturers as well as the understanding in the industry as to what a compliance -- an effective compliance program is.

Q. As far as understanding in the industry, is there other -- other written documents that you cite other than the OIG guidance and the Sentencing Guidelines that

could help me understand what "effectiveness" means?

MS. JUDE: Objection to form.

Q. You can answer.

A. Okay. I'm sure that there are other documents that are referenced in these materials. If you can point me to a particular document, I'd be happy to discuss it.

The concept of effectiveness is something that was enumerated, if you will, in the Sentencing Guidelines, outlined in the Sentencing Guidelines, and "effectiveness" has grown to mean since the time of the Sentencing Guidelines, which I think was 1991, to mean the -- whether or not a compliance program does what it's supposed to do in this sense: That it not only sets forth a framework of standards, but those standards are tested and to see whether or not in fact they work. So effectiveness is really a function of is the compliance program working.

Q. Okay. And were you retained by the U.S. Attorney's Office in this matter?

A. Yes, I was.

Pharmaceutical Guidance was drafted.

Q. Okay.

MS. JUDE: I just want to put an objection on the record to the extent that this is using Ms. Evans' expertise in this case to try to prove that certain elements of the case are not met.

I mean, she is a lawyer so obviously she can answer these questions. I don't think I need to make them as to form on the record, but she's here purely to offer an opinion about compliance and not about --

MR. GRUENSTEIN: I understand that.

MS. JUDE: -- this case.

MR. GRUENSTEIN: I understand that.

BY MR. GRUENSTEIN:

Q. I want to ask a question that I may not have asked clearly before about your methodology of determining whether a company has an effective compliance program.

I assume you've considered other companies and whether other companies have effective compliance programs?

A. Yes, I have.

Q. And what is your methodology for that consideration?

A. Well, one of the first things that I would do -- that I do is to take a look at the policies and procedures. The very first element of the -- of an effective compliance program, the first element that's enumerated, I would take a look at those.

It would be my practice then, if there were no depositions, to interview individuals in the organization. If there is -- if that's not an option, the next thing I would do is look at statements from the individuals, and based upon those statements, I would then seek to review documents. And those could be e-mails, they could be training materials, the documents could be financial analyses, complaints, responses to the hotline, investigations, and then any remediations that occurred as a result of those complaints and look to determine whether or not the compliance program has an internal ability to use information gleaned from all of these sources in statements about risk, documents, materials, e-mails, complaints, investigations,

take all of that information and wind it back into their compliance policies and training and education so that you have some ability to state with confidence that there was a problem, the problem -- a compliance problem, the problem was reviewed, corrective action was drafted, and then a testing after the corrective action was determined and implemented to see if it's working, basically.

Q. So I want to take you out of the context where you're doing that review and litigation as an expert witness.

A. Okay.

Q. Because I assume as a consultant you do this analysis for companies?

A. That's correct.

Q. Okay. And when you do that analysis, you typically will interview people?

A. That's correct.

Q. And presumably you interview key people at the company who deal with the compliance program, correct?

A. Yes.

Q. So, for example, you would interview

the chief compliance officer?

A. That would -- yes, uh-huh.

Q. And you interview other people in the Compliance Department?

A. Yes.

Q. You interview people in Internal Audit?

A. Sometimes, yes.

Q. And you interview people in Human Resources, perhaps?

A. Sometimes, yes. It really depends on whether or not the compliance program touches those areas, and sometimes it does and sometimes it doesn't. That would be true of both Internal Audit and HR.

Q. And there may be other departments that you would say touch on compliance like, for example, Legal, Finance, maybe others, correct?

A. That's correct.

Q. And there may be times where for you to do a thorough review of a compliance program you have to interview dozens of people, correct?

A. That's correct.

Q. And you review -- you ask -- I'm

sorry. Let me strike that.

You ask those people to provide you with all relevant policies, correct?

A. Yes.

Q. And then you review those policies thoroughly, correct?

A. Yes. Try to.

Q. And you ask for documentation of instances where there were violations of the policies, correct?

A. Sometimes, yes. Uh-huh.

Q. And you review the investigation reports, if there are investigation reports?

A. Yes.

Q. And that all informs your decision as to whether the company is or is not effective, correct?

A. It helps to -- helps me to come to a conclusion as to whether or not it -- the compliance program is working, yeah.

Q. Okay. Do you ever take proactive steps like issuing a survey to employees?

A. Yes, that is something that I have been involved in with other organizations in the

past, uh-huh.

Q. And is that helpful for you to determine whether there is a culture of compliance at the company?

A. Yes.

Q. And whether there's a culture of compliance at the company is certainly something that you consider when you're considering whether there is an overall effective compliance program?

A. Yes, that is something that, although culture of compliance is kind of difficult to -- to describe, you know, you --

Q. You know it when you see it?

A. You know it when you see it.

Q. Okay. I feel that way about a lot of the --

A. Right.

Q. -- a lot of the factors that are involved.

And when companies ask you to review their compliance program, at the end of the day, you give them suggestions for improvement?

A. Yes. Yes. Or I may suggest to them

that they need to do a deeper dive into particular areas because there is apparent risk.

Q. And that itself is a suggestion for improvement?

A. Yes, sir. Uh-huh.

Q. And do you ever say to a company, "Your compliance program is effective. There's nothing more that you need to do"?

A. I have been involved with companies that have excellent compliance programs that are effective, that need very little adjustment.

Q. Okay. Unfortunately, those companies never need to hire me because they never get into any trouble, so I haven't encountered them, but okay.

But it's fair to say that you also have had clients -- I'm talking about consulting clients, not legal clients -- I don't want to tread on the privilege -- but you have had clients where you would conclude that they had effective compliance programs, but there was still room for improvement?

A. That's correct.

Q. And then you've had other clients

that -- well, let me ask you, have you had other clients where you have reached the conclusion you have an ineffective compliance program?

A. Absolutely.

Q. Okay. And you've given them room for improvement -- you have given them ideas for improvement?

A. Yes, I have.

Q. So it's possible that an effective compliance program has room for improvement as well as an ineffective compliance program, correct?

A. That is possible.

MS. JUDE: Object to the form.

THE WITNESS: I'm sorry.

MS. JUDE: Objection to form.

THE WITNESS: That is possible.

BY MR. GRUENSTEIN:

Q. Of course, the ineffective program has more room for improvement --

A. Yes.

Q. -- than the effective, correct?

A. Yes.

Q. How do you draw the line between an

effective compliance program and an ineffective compliance program?

A. If I'm observing a program and it appears that there is a risk that laws are being violated or that regulations are being violated and that this is not an isolated instance, that it is a pattern of behavior, and there doesn't seem to be anything within the organization that is an internal control or compliance control on the activity, then at that point, I conclude that it's ineffective and that the company needs to address it, so...

Q. So you said, you know, first that there's a risk of illegal activity happening?

A. That's correct.

Q. Is it fair to say that at every company there is a risk of some sort of misconduct happening. The only question really is how well-controlled that risk is?

A. I think that there are companies where that risk is very, very limited because of the way that their -- they operate their programs.

Q. Okay. But I'm saying before -- well, maybe I don't need to clarify it, so I'll move

on.

But you also said in your last answer that where there are no controls that are addressing the risk, you would determine that the program was ineffective, correct?

A. Well, if it's a -- if it's a control and it's not addressing the risk, then it's not really a control as that is -- term is understood in auditing. It's not -- it's not an accurate control.

I'm not an auditor, but I understand that concept, that there needs to be a check, if you will, on an activity; and if there is no check, then it's not adequately being controlled and the risk is allowed to grow and continue and is not being addressed.

Q. But how do you draw the line between a company that has adequate controls that address the risk and a company that does not have adequate controls to address a risk?

A. One of the primary ways that you can determine whether or not a company has adequate controls to address the risk is by looking to see whether it's testing those risks and testing

the controls or testing the behavior, if you will, and so you -- you isolate whatever particular behavior it is that you're looking at and then take a sample of the instances of that behavior.

And you might -- it might be a targeted sample. You might have information from a different source from, you know, word on the street or the hotline or whatever that there's an issue with a particular individual or there's a particular region.

Then you take a look at that -- the universe of claims or whatever it is you're looking at and you determine if there is in fact a risk, and if there is a risk, why isn't it being addressed and what could be put in place that would prevent this behavior from happening.

Then I think a competent compliance officer would then take a look again at the corrective actions and determine whether or not the corrective actions have done what we were hoping that they would do, which is address the risk.

And those corrective actions could be

additional training. It could be, you know, asking for supervisory approval. It could be getting management pre-approval for behavior. Whatever it is, you're looking to see that you can address it through some control.

Q. Okay. So, I mean, you have listed several things that you would look at, but at the end of the day, if you're asked to make the determination is the compliance program effective or is it not effective, how do you decide if the program is on one side of the line or another?

A. Do they have controls? If they have controls, are they being implemented? If the controls are being implemented, are they effective? Do they do what they were designed to do?

Q. Okay. So you have asked -- you have asked three questions. So do they have controls?

A. Right.

Q. That's a question you would look at. Well, are there policies and procedures in place. That would be what you would look at,

A. Yes, sir, although I believe that other folks participated in the policy drafting later on. By that I would say after 2005, and I don't know how -- how many years into or past 2009, 2010 he remained in the policy-making position.

Q. So if Marty and others thought that these policies were not ambiguous, but then the people you cite thought that the policies were ambiguous, why do you rely on those people and not on Marty?

MS. JUDE: Objection to form.

A. Because when looking at the effectiveness of the policies, it was apparent to me based on subsequent e-mails and other deposition testimony that the sales reps were having a difficult time understanding what was meant by some of the policies.

So they had a difficult time understanding what was meant by "occasional" and an "occasional meal." They had a difficult time understanding who was a legitimate attendee, for example, so -- and then very simple policies like the gifts policy. No gifts? Some gifts?

Gifts under $100? There were varying interpretations of when it was appropriate to provide gifts, and there were many occasions that I saw in the materials where Mr. Putenis even deferred to Sales and said, you know, let's let Sales make that determination.

Q. You didn't review any depositions of sales reps, did you?

A. I did not.

Q. And if there were depositions of sales reps where they gave the proper interpretation of these policies, how would that influence your analysis, if at all?

MS. JUDE: Objection to form.

A. In my opinion, based upon the policies that I reviewed and the information that the compliance folks had at the time and were discussing and were discussing with senior management, I think that the policies were inadequate, as Mr. Hollasch said. I think that they could have been clearer.

Q. And how does Mr. Hollasch's opinion inform your opinion?

A. At one point, they were talking about

coming up with more specific modest meal policies, and Mr. Hollasch in an e-mail, fairly late in the review period, maybe it was 2009, said let's push off this modest meal policy effort because the policies that we have now are clearly inadequate.

And that's someone at the time on the scene who's writing about attempting to address a problem that he was aware of because of the earlier internal audit issues that occurred during the 2008 field audit.

So, yeah, I -- at that point in time, that slice in time, it looked to me like the compliance officers were having difficulty getting the sales reps to comprehend the policies.

Q. Okay.

A. And maybe that's because the policies were not very clear.

Q. As a -- as a compliance consultant, you are involved in helping companies draft their policies, correct?

A. Yes, sir.

Q. And it's certainly the case that a

policy cannot prescribe what an employee should do in every situation; some amount is left to the discretion of the employee, correct?

A. That's generally true unless you have an instance where you know that you're putting individuals who are -- are going to be conflicted because of their inherent role in a position where they're making decisions, and what -- it is often helpful in those circumstances to give a couple of examples or to further define what is meant by "occasional."

Q. Okay. So, in the last sentence of the paragraph, you say, which I think is consistent with what you just said, "In general, leaving room for subjective interpretation of policies designed to prevent fraud is antithetical to an effective compliance program particularly where interpretation is in the hands of sales reps or managers who are compensated based on sales or business goals, and thus are incentivized to interpret policies in a sales-friendly manner."

Correct?

A. That's correct.

Q. And is that principle contained in any

at speaker programs to your recollection?
A. I know that one did. I don't know about the other ones.
Q. Do you remember what the number was with that one?
A. No, I don't.
Q. Okay. Do you think it was higher than three, or you don't recall?
A. I don't recall.
Q. And was there any -- is there any guidance that you can point to that says that the number of legitimate attendees is relevant to AKS risk?
MS. JUDE: Objection to form.
A. Once again, I'd go back to the 2003 pharma.
Q. OIG?
A. OIG Guidance. And also, there was internal information and documents from Novartis, from NPC, where the number 3 was identified as being the target number that put them in a position where they felt the risk was acceptable and that they could legitimately explain the speaker program as being a bona fide

program where scientific information was imparted to other physicians.
Q. Let me just back up and ask you a -- kind of a methodological question.
Your overall opinion is that NPC's compliance program was not effective as it related to speaker programs?
A. Uh-huh.
Q. Correct?
A. Right.
Q. And now we're walking through the seven elements of a compliance program, correct?
A. Right.
Q. Do you -- did you draw a conclusion about the effectiveness of each one of those elements?
A. I did, but there's a caveat. I looked at them sequentially, so I looked -- rather than breaking it down into individual elements at the outset, I looked at the speaker program across time and then went back and looked at the individual elements, speaker program compliance over time. So, yes.
Q. So the reason I ask is because on page

10 you say on the first paragraph, the second line, "NPC's minimum attendance policy was deficient," and then you explain why.
Is "deficient" just another word for saying "not effective"?
A. Yes, that was just the choice of the word that I used.
Q. Okay. If we look at the next paragraph you -- you talk about a development or developments in the -- in the policies as it relates to legitimate attendees.
Do you see that?
A. No, I -- where are you?
Q. In the next paragraph.
A. Uh-huh.
Q. "Prior to 2003, NPC had no requirement for a minimum number"?
A. Oh, okay. Uh-huh.
Q. Then, starting in 2003, there had to be at least three healthcare professionals?
A. Yes, sir.
Q. And the interpretation of healthcare professionals was left up to the sales force, you saw that?

A. Yes.
Q. And then in 2004, "healthcare professionals" was defined as those with prescribing rights, but the minimum requirement was loosened because -- by permitting speaker programs to proceed without three legitimate attendees if the sales rep had made a good faith effort to ensure minimum attendance. Do you see that?
A. Yes.
Q. And in your opinion, or are you expressing an opinion that there was something problematic about having that good faith exception?
A. No, I was just pointing out that factually that was what was occurring at that point in time. So the term "healthcare professionals" was further refined in the policies as those with prescribing rights. So I thought that was a positive effort.
"...the minimum required -- requirement was loosened by permitting Speaker Programs to proceed without the three legitimate attendees if the sales rep had made a 'good

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MS. JUDE: Objection to form.

A. No, I wouldn't say speaker programs specifically, but certainly promotion, promotion by physicians.

Q. And was there any written guidance that suggested that this was a risk, having, you know, prescribers of -- let me rephrase the question.

Was there any sort of written guidance that said, you know, there's a risk that, you know, colorectal surgeons are going to show up at Prozac speaker programs, you better watch out?

MS. JUDE: Objection.

Q. Because, you know, there's -- you know, those aren't the types of doctors that prescribe Prozac?

MS. JUDE: Objection to form.

Q. Do you remember any written guidance to that effect?

MS. JUDE: Same objection.

Q. Your counsel has an objection, but you can answer.

A. I don't recall the specific guidance.

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I know that at the Healthcare Compliance Association and American Health Law Association meetings that I attended, the idea that speaker programs and other meetings could be padded was very much discussed, and the idea of off-label and sort of benefits to being provided to physician speakers without a business justification was something that a lot of folks were talking about.

Q. Okay. Let's look at the next page in the final paragraph. In the last sentence, you say, "Until 2011, NPC's minimum attendance policy for Speaker Programs was not effective at managing the risk that promotional events could be used to provide payments to HCPs for illegitimate purposes."

Do you see that?

A. Yes.

Q. Earlier you testified that one of the questions you asked in an effectiveness analysis is, well, ultimately, what happened?

And is that what you're getting at here?

MS. JUDE: Objection to form.

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A. One second, please.

Q. Yeah.

A. Yeah, I think that -- I think that it was not an effective policy. It did not necessarily ensure the idea that speaker programs were going to be legitimate events that were used to educate other physicians about the benefits of a particular product, and so, yes, I don't think that the program was effective.

Q. And did you analyze any data about whether, you know, either non-prescribers of the drugs were showing up to pad numbers or that the minimum three wasn't being met?

A. I actually did, yes, I did look at data and looked at information not only from the third quarter 2008 audit that was conducted by Natalie Nelson-Ling -- Lang -- and David Hollasch, but I also looked at information from Mr. Goldberg, Richard Goldberg, who was another government expert, that showed that the minimum attendance policy was in fact an issue, so...

Q. Do you -- did you do anything to benchmark those data analyses against how other companies were doing at the time?

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A. I did not.

Q. Let's look at the next section, "Policy Regarding Guests"?

A. Excuse me. I'm sorry. I didn't mean to interrupt, but I believe that Julie Kane actually had done an analysis, and so I reviewed an e-mail that she provided I believe to the CEO analyzing the different policies that NPC had against other pharmaceutical companies.

I don't know what those pharmaceutical -- who those pharmaceutical companies were, and I certainly didn't check her data, but I used Novartis' own materials to that extent.

Q. Okay. To be clear, in your report you don't draw a conclusion as to whether Novartis' compliance program was more or less effective than other pharmaceutical companies' compliance programs during this time, do you?

A. I did not.

Q. Let's look at the next section, "Policies Regarding Guests."

A. Okay.

Q. You talk about the 2001 and 2003

guidelines contain no general prohibition against a guest or a spouse attending a speaker program, and there's evidence that NPC regularly allowed spouses to attend at that time.

Was there any guidance in 2001 prohibiting the attendance of a guest?

MS. JUDE: Objection to form.

Q. That you're aware of?

A. Yes, but again, I would refer to the HHS OIG 2003 Compliance Guidelines. I would also point out that the PhRMA Code at this -- back in 2002 stated that spouses and guests should not be -- should not attend.

Q. And did that guidance say they should not attend, or if they attend, it should be not be paid for by the company?

A. I don't believe that there's any business reason. I mean, if the reason that you're paying for the dinner and conferring a benefit on a physician is because it is an accommodation to that individual during the course of a business meeting where he or she is providing information about a particular drug and its benefits and safety issues to other

providers, there's no legitimate business reason for a spouse or a guest to be there. Therefore, I would say that that benefit triggers an anti-kickback violation -- or, sorry, anti-kickback risk.

Q. Okay. But you're not testifying here as a lawyer, correct?

A. I'm sorry?

Q. You're not testifying here as a lawyer?

A. No, sir.

Q. But my question was not about what you thought, but rather what the Pharma Guidance was in 2002?

A. Well, and --

Q. PhRMA Code guidance. Sorry.

A. The PhRMA Code guidance, I don't know whether it prohibited. I believe it prohibited. It said that spouses and guests should not be invited.

Q. Okay. Let's look at "Repeat Attendance," Section 3.

A. Okay.

Q. In the first sentence, "During the

Review Period, NPC's Compliance Policies failed to control for a serious AKS risk," and then you describe repeat attendance. Do you see that?

A. Yes.

Q. Are you familiar with any written guidance that says that repeat attendance is a serious AKS risk?

MS. JUDE: Objection to form.

A. Again, I would refer to the 2003 HHS OIG pharma manufacturers -- compliance guidance for pharma manufacturers, and also the PhRMA Code. I believe the 2009 code referred to occasional meals. And finally, to Novartis' own policy, NPC's own policies, that talked about occasional meals for healthcare providers and occasional dinners in the context of speaker programs.

Q. Did you ever advise your pharma clients about what "occasional" means for purposes of the PhRMA Code guidance?

A. Well, I certainly would not -- I'm sorry. Strike that.

Did I ever advise...

I -- I can -- I don't know if I ever

used the word "occasional." Sorry. I don't know if I ever used the word "occasional," but I can state that I have advised pharma and other entities who were providing -- who were in a position to provide benefits to healthcare providers that this is not something that should be done outside of the context of a business meeting on a regular basis.

So --

Q. Okay.

A. -- dinners and things of that nature, repeated events.

Q. Do you recall advising your clients about repeat attendance by doctors at the same program?

MS. JUDE: Objection to form.

Q. If you recall.

A. And I am concerned because I don't want to violate attorney-client privilege with respect to some of my service as a compliance officer and general counsel for Centra, so I'm just thinking about how to answer this question.

So, I'm sorry, can you repeat the question maybe?

MR. GRUENSTEIN: I'm sorry. Can you read it back?

(Record read.)

Q. And I can limit it if it helps you on the attorney-client privilege to your consulting clients.

A. No, I don't recall providing that guidance.

Q. Do you recall the testimony of Natasha Nelson-Ling where she said -- she was asked about repeat attendance and said, you know, I -- I wish I had looked into it, but I didn't know that that was a risk until the U.S. Attorney's Office brought this case in 2000 -- whatever it was?

MS. JUDE: Objection.

Q. Do you recall that testimony?

A. Yes, I do.

Q. And what was your reaction to that, to reading that testimony?

A. I -- actually, I believed that Natalie Nelson-Ling and others in the compliance program had minimized this risk, and that was kind of surprising to me because there was a lot of

material in the e-mails and in other documents, complaints, pharma -- CafePharma complaints, where people were talking about these repeated speaker events.

There was one particular instance involving a Dr. [redacted] where the investigation revealed that some of the doctors had gone to a -- a small group of doctors had gone to 23, 24, 25 events in a year, and that just did not make sense to me from an anti-kickback risk perspective.

Q. But just to be clear, that's based on Novartis internal materials, correct?

MS. JUDE: Objection to form.

A. I'm sorry, what is?

Q. What you just answered is you were surprised that compliance people didn't recognize the risk given all of the internal e-mails and findings that were going around Novartis, correct?

A. That's correct.

Q. But what I'm asking is, were you surprised that she hadn't heard, let's say, in a CIA or in other written guidance that repeat

attendance was a serious AKS risk?

MS. JUDE: Objection. Misstates testimony.

A. I'm sorry, I have forgotten the question.

Q. I'll ask a -- I'll ask a slightly different question.

Was there any written guidance or indication in a CIA during the review period that repeat attendance by doctors at speaker programs was an AKS risk?

A. I don't know the answer to that question. I have not reviewed all of the CIAs. There were many, many during the time period, so...

Q. Let's look at the next page, 13.

A. Uh-huh.

Q. In the first full paragraph, you say, in the second sentence, "In my opinion, it is also clear from the materials that NPC was aware that repeat attendance prevented ser- -- presented serious compliance risks."

Do you see that?

A. Yes.

Q. And what is your opinion there, if you could explain it?

A. Are you asking me to restate my opinion, sir?

Q. Well, I'm asking you to explain what you're saying. You say that NPC was aware.

Are you -- is that a conclusion about the company's knowledge?

MS. JUDE: Objection to form.

A. No, I'm actually -- what I was actually doing there is indicating a reference factually that -- referencing some of the information that I've talked about earlier that not only Natalie Nelson-Ling, but the "do's and don't's" document do not hold meetings on a recurring basis.

There was another one. Yes, it was Maria Woods when she was talking about -- and I think she had conducted an investigation and concluded that there wasn't sufficient information to substantiate the investigation as a compliance violation, but she said it appears that hosting the same individuals repeatedly at the same time at the same presentations may be

problematic because it creates the appearance of providing honoraria to speakers for illegitimate programs, kickback issues. So this was something that came up.

Also, they -- they did add to this FLM Dashboard information that, you know, to prevent repeat attendance because that would not comply with the occasional meals policy. So I think the occasional meals policy itself is a recognition that if you have repeated programs, same speakers, same drug, same attendees, then there may be an argument by some regulator or other person looking at the risk that this activity violates the Anti-Kickback Statute.

Q. Okay. But to be clear, I mean, you say, "In my opinion it is clear from the materials that NPC was aware."

It sounds like what you're saying now is, in your -- based on your review of all the documents and depositions cited in footnote 50, it seems that people at NPC were aware of this compliance risk; is that correct?

MS. JUDE: Objection to form.

A. I think that's right.

I'm sorry.

MS. JUDE: Go ahead.

A. I think that's right, yes.

Q. Let's go to "Venue," which is on page 14.

A. Okay.

Q. And this section is called 4, "Venue and Entertainment Policies."

A. Uh-huh.

Q. And what you -- in the first paragraph, you say, "NPC's Speaker Program policies did not properly manage the risk of conferring this benefit," which is -- the benefit that you're referring to is the -- the entertainment?

A. Uh-huh. Yes, sir.

Q. "...because entertainment was permitted for some types of events until 2008 and because sales representatives were allowed to apply their own judgment."

Do you see that?

A. Yes.

Q. And when you say "did not properly manage the risk," is that another way of saying

was ineffective?

A. I believe, yes, that is the same thing as saying it's not an effective compliance program.

Q. Okay. And then in the next paragraph, you say at the end of the paragraph that the decision to permit sales reps to exercise their judgment about proper -- about appropriate entertainment when their comp was based on volume of drugs prescribed by attending HCPs was a poor way to control anti-kickback risk.

Again, when you say "poor way to control anti-kickback risk," that's another way of saying ineffective, correct?

A. That's correct, uh-huh.

Q. You, in the next paragraph, you talk about how, in 2003, NPC's policy, these healthcare compliance guidelines, incorporated language from the PhRMA Code that promotional events should be held at "venues conducive to an exchange of medical information but also allowed modest entertainment such as golf."

Do you see that?

A. Yes.

Q. As you're measuring the effectiveness of the compliance program, does it fall on the positive side of the ledger that Novartis' policies were at least incorporating the language and the guidance from the PhRMA Code?

MS. JUDE: Objection to form.

A. I think it's positive to the extent that NPC was using language from the code and trying to conform its policies to the code, yes.

Q. Okay. And then you say, "Later NPC policies provided modest entertainment may be appropriate if approved by the Events Oversight Committee. The rationale supporting these exceptions to the no-entertainment rule is unclear."

Do you see that?

A. Yes.

Q. And when you say the rationale is unclear, do you mean that you weren't able to find anything in the record explaining why there might be exceptions approved?

A. Yes, that's correct. Mr. Putenis seemed to state that, in certain circumstances, entertainment would be appropriate and then in

other circumstances, it would not be appropriate and there seemed to be a distinction made for golf.

So it was -- it was not clear to me reading the compliance policies and reading the PhRMA Code, the 2002 PhRMA Code, and then later the 2009 PhRMA Code, why there were some exceptions for entertainment. That was just not made clear.

And I put myself in the position of a sales rep trying to comply with the rules and, you know, was -- was unclear what Mr. Putenis and the Compliance Department was telling me to do.

Q. Do you know --

A. Sounded like golf was okay sometimes but it wasn't okay other times.

Q. Do you know how common it was for the Events Oversight Committee to approve these exceptions?

A. Well, the Events Oversight Committee did not approve the standard garden-variety speaker program dinners that I think we're talking about. I think the Events Oversight

Committee was really focused on speaker training and what benefits were -- entertainment were provided during the course of the speaker training, and also what Mr. Putenis and others described as exceptional or, you know, larger events as opposed to -- I remember seeing a PowerPoint as well as other information that indicated that NPC exempted regular dinner speaker programs or roundtables, for example, from oversight by the Events Oversight Committee.

Q. Okay. Just going back to my question. Do you know how common it was for the Events Oversight Committee to approve exceptions to the no-entertainment rule?

A. I do not know.

Q. You then, in the next paragraph, you say, "NPC generally left determination of what venues were appropriate up to sales representatives."

Do you see that?

A. Yes.

Q. Do you know, the other companies that you provided consulting advice for, do you know

how they restricted venue choices during this period?

A. No, I do not.

Q. To be clear, the two companies that you provided -- the two pharma companies that you provided compliance advice to, what years was that roughly? Again, I'm not asking the identity, but what years?

A. One second.

Q. Or if it's easier, where were you working?

A. KPMG, Daylight, and Ober.

Q. The next section 5 is on "Modest Meals and Aggregate Spend Policies?"

A. Uh-huh.

Q. And your finding looks like -- it looks like you have two negative findings, if I'm reading correctly. One, the policy failed to define modest; and, two, it did not address the practice of splitting bills to circumvent the -- what was ultimately put in, which was a cap on per-person spending.

Do you see that?

A. Yes.

Q. Do you know how other companies were defining "modest" during this period?

A. I actually do know that $125 per person was a range that was not out of the ballpark at that point.

Q. Okay.

A. For meals outside of the office.

Q. And how do you know that?

A. From my general knowledge and experience in the business, so...

Q. And in the early period, where it says NPC's early policies, I assumed you were referring to the first few years of the review period, you say that they failed to define "modest."

Do you know whether other companies were defining "modest" at that time?

A. I do not know the answer to that question.

Q. Let's look at -- the next section is "Honoraria Amounts"?

A. Right.

Q. And if you look on the bottom of the page 17, you're talking about fair market value?

A. Yes.
Q. And is it accurate to say that in 2010 Novartis changed the policy to reflect the development in 2009, which you cite in footnote 82?
MS. JUDE: Objection to form.
A. Yes, they did change the policy to reflect the fact that they were not counting the compensation paid towards speaker training, which was also to be counted not only, as I understand it, for state law reporting purposes, but also to get a fix internally in terms of compliance and finance on how much they were actually paying the speakers.
Q. Let's talk about the next Section 7, "Speaker Selection and Performance"?
A. Okay.
Q. In the second paragraph, you say, "In the absence of policies, the Compliance Department deferred to Sales on these matters."
Which is a reference to speaker selection, correct?
A. Yes, and also speaker performance.
Q. Okay. And I notice, despite your very

impressive number of footnotes, you don't have a footnote for that sentence, so I was wondering what are you relying on for that factual assertion?
A. Well, I would have to go back and go through all of the footnotes, which I don't think we need to do at this point, but to explain the -- the lack of effectiveness, the speaker policies did not address speaker selection until later on, and I think -- well, throughout the sales -- throughout the review period, the sales reps were permitted to nominate healthcare professionals to serve as speakers and that can be and was, in fact, a real benefit to some of the speakers?
(Knock on the door.)
A. Continue?
Q. Yes, please.
Maybe -- maybe I should ask another question because I think maybe you lost your train of thought, as did I.
A. Okay.
Q. Yeah, go ahead.
A. And also, with respect to performance.

The speaker performance issues were really left to the sales reps for throughout the bulk of the review period. They had to deal with speakers who weren't showing, speakers who deviated from the slides, speakers who did ten minutes.
It was really left up to them, which is a hard position to put them in given that their compensation is determined in part by how many speaker programs they had as well as the prescriptions.
Q. So then on the top of 20, you say, "In my opinion, sales associates should have been taken out of the speaker program -- speaker selection process entirely. HCP requests for speaking engagements should have been referred elsewhere in the organization."
Do you know whether other companies were doing that at this time?
A. I do not know the answer to that question.
Q. And then in the next paragraph, at the end of the paragraph, you say, "The best way to avoid this risk would have been for someone other than the sales associates to select

speakers."
When you say "the best way," that's like saying the best practice would have been?
A. Yes, I think so. It would have been a better practice and maybe the best practice to have an outside group, not necessarily the speakers, selecting -- I'm sorry, not necessarily the sales reps selecting the speakers.
That way you would have been able to make sure that you're meeting the criteria enumerated in the PhRMA Code and the HHS OIG Guidance, you know, having someone who is known in the field, someone who is experienced, someone who is a good speaker, who is reliable, who shows up.
Q. Okay. And do you know of any written guidance that says that that would be the best practice?
MS. JUDE: Objection to form.
A. No, I don't. Not off the top of my head, I don't.
Q. And going back to a question I've been asking you a lot, which is your opinions about

effectiveness, saying that something was not the best practice, that's not equivalent to saying that it was ineffective, was it?

A. No, that's correct.

MR. GRUENSTEIN: Okay. Now may be a good time for a break, if we can go off the record.

THE VIDEOGRAPHER: The time is 12:01 p.m. We're going off the record.

(Recess.)

THE VIDEOGRAPHER: The time is 12:14 p.m. We're back on the record, video number 3.

BY MR. GRUENSTEIN:

Q. Ms. Evans, just to follow up on a point you made earlier about the sales reps had incentive-based compensation, what do you know about the compensation of sales reps during this review period?

MS. JUDE: Objection.

At Novartis?

MR. GRUENSTEIN: Yes.

THE WITNESS: I reviewed materials that were provided about the sales reps'

compensation, including presentations that were made to them to explain their compensation, and so I understand that it was pretty complex, but there was a component of their compensation during the review period that had to do with whether or not they were using up the money that was allocated to them for the speaker programs, that they were having the appropriate number of speaker programs, and that their compensation was also based on the number of sales, including prescriptions by the speakers and other folks who were in attendance at the programs.

BY MR. GRUENSTEIN:

Q. And do you have a sense of how those various components were divvied up?

A. I really don't off the top of my head. I would have to look at the document.

Q. Okay.

A. And I'm happy to do that if you'd like to do that.

Q. Let's go to page 21. We're now on -- we're off of policies and on to the compliance

departments and officers. Do you see that?

A. Yes, sir.

Q. And we can go to the second sentence, which says that, "An effective compliance program begins with a formal commitment by the Board of Directors or other governing body, including the allocation of adequate resources," and then it goes on.

Do you see that? Do you see that sentence?

A. Yes, sir.

Q. And did you for purposes of your review consider the resources that Novartis put towards its compliance program?

A. I -- the answer to that would be yes, to the extent that I looked at the number of folks who were assigned to address compliance issues within NPC.

Q. And did you look at, for example, how many millions of dollars Novartis spent on compliance during this period?

A. No, I did not.

Q. Let's go to page 25, footnote 111. And just to orient you, you're talking about

that Novartis had an OIG Readiness Task Force, but not -- but it did not serve as a compliance committee.

Do you see that?

A. Yes.

Q. And then later down in the footnote, you say, "In my opinion, the OIG Readiness Task Force appeared to be mainly 'window dressing' in the event of review by government regulators."

What are you saying there and what did you base that statement on?

MS. JUDE: Objection to form.

A. As I understand from my review of the documents and the depositions, but mostly the documents, the OIG Readiness Task Force was a group that was put together in response to the drafting of the HHS OIG, or the -- I'm sorry, the implementation of the HHS OIG Compliance Guidance for Pharmaceutical Manufacturers, and I understood based on the documents that there was a meeting in Washington, D.C., and at the conclusion of that meeting, I don't know who was present at that meeting, I just reviewed notes from the meeting, and at the conclusion of the

meeting, NPC compliance personnel came back to their offices, wherever that was, and put together some efforts to address some of the items that had been raised at the meeting, the OIG meeting, and those were particularly in response to the 2003 guidance.

So one of the things that they did was create this OIG Readiness Task Force, which had various components and folks assigned to it. It did not really appear to me to be a compliance committee as is described in the OIG guidance, although, excuse me, I did -- I did see a reference to the OIG Readiness Task Force then became the Commercial Compliance Committee around the time of the Novartis report.

Q. But when you say that it appeared to be mainly window dressing in the event of review by government regulators, did you mean that the people who put it together did so not for really legitimate reasons, but just to have it in case they needed to show regulators down the road?

A. That was my sense, that this was an effort to have something in place because they knew that HHS OIG had these guidelines and they

were going to scrutinize the performance of pharmaceutical manufacturers based upon the guidelines. So they needed to have something in place, and this was how they were starting to do that.

Q. Let's look at the next page, and there's a sentence -- it's in the middle of that first top paragraph that starts with "Mr. Putenis."

A. Yes, sir.

Q. You say, "Mr. Putenis testified that sales reps were told not to use speaker programs as a reward for prescribing or induce physicians to prescribe, but did not acknowledge that using high prescribers as speakers presented a serious compliance risk, instead emphasizing the importance of permitting NPC to use speakers with 'experience with the product' for effective marketing."

Do you see that?

A. No, actually, I don't.

Q. I read the whole thing and you didn't even see it.

Page 26.

A. Sorry.

Q. The top.

A. Okay.

Q. The middle of that first --

A. "Mr. Putenis testified."

Q. Yeah.

A. Okay. I got it.

Q. So what I'm going to do -- and you cite to footnote 117, pages 210 to 214, which I'm going to give you the transcript of that.

A. Okay.

Q. And what I want to do, if we can just look at what you rely on for a minute.

A. Okay.

Q. And I'd like to understand your statement that he did not acknowledge that using high prescribers presented compliance risk in light of a few paragraphs that I'm going to point you to.

A. Okay.

Q. So if you look at 211, at line 4, Mr. Putenis says --

Do you see it?

A. Uh-huh.

Q. "Sales reps would be instructed that they cannot use speaker training initiatives as a vehicle for rewarding people for prescribing or by inducing them to prescribe any particular product."

Then on the bottom of 212, it says, "We emphasized to our salespeople that they may not utilize invitation to a speaker training event or contracting with an individual healthcare professional to serve as a speaker as a reward for past prescribing or as an inducement to get them to prescribe our product."

A. Uh-huh.

Q. And then on page 214, starting with line 15 -- this is actually after the part that you cite. There's a question -- I won't read the question. I'll just go to the line 23.

Mr. Putenis said, "The requirement was that they may not select people to serve as speakers or to participate in speaker training for the purpose of rewarding them for past prescribing or inducing them for future prescribing."

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So, in light of those paragraphs, what did you mean when you said that Mr. Putenis didn't acknowledge this compliance risk?

A. Well, if you go back to page 211, Mr. Putenis also said -- stated that he understood, or, "We understood that the credibility of a speaker is enhanced if they have experience with our product, and that credibility is lost if they stand before an audience that have no experience in prescribing the product. So that is a relevant measure of the attractiveness of a particular person to serve in a speaker role for Novartis. It stands to reason that we would consider whether or not a doctor was a prescriber or -- whether a doctor was a prescriber or not when selecting them to serve on our speaker bureau."

So -- so then -- and then there were also a series of questions where the attorney who was doing the deposition asks about whether or not, as long as the speaker's reps -- I'm sorry. Strike that. As long as the sales reps are not selecting a speaker as an inducement, it's okay for a sales rep to select a speaker

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simply because the speaker is a high-volume prescriber of Novartis drugs, and Mr. Putenis would not agree with that.

And then when they asked is it not okay, and he wouldn't agree with that either. So he also said high prescribing would never be the sole basis on which the person is selected, so -- and then the person who asked the question said: "Well, if it was, would that be a violation of Novartis' guidelines?" The answer was, "Not necessarily." "Under what circumstances would it not be a violation?" And again, Mr. Putenis said, "Because there are speakers that are preferable for us who have experience with the product, and that is a determination that's based on whether or not they prescribe."

Q. So would you agree with me that, in these five or six pages, he does say that it's okay to rely on the fact that a doctor has prescribed the drug to choose them to be a speaker?

A. Yes, he does say that, that experience with the product is something that they were

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looking for.

Q. And he also says that people were told that they could not choose the speaker as a way of rewarding people for having been high prescribers, correct?

A. That's correct.

Q. But is what you're saying in the report that, based on your reading, it looks like he did not emphasize the compliance risk associated with rewarding high prescribers for prescribing by choosing them to be speakers?

A. That's correct. I did not feel like he recognized the risk, or if he recognized it, did not describe it adequately to the sales reps.

Q. Let's look at section B, Julie Kane.

A. Okay.

Q. And as a consultant, are you asked to consider the effectiveness of compliance officers?

A. To the extent that I'm looking at the effectiveness of a particular compliance program, and there are issues with respect to the leadership or competence or enthusiasm of

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the compliance officer or the manner in which he or she presents the compliance communication message, yes, I do look at -- at the compliance officers and the department in general, departments in general.

Q. And presumably when you do that, you interview the compliance officer?

A. Yes, sir.

Q. And do you presumably interview the -- some of the people that report to the compliance officer?

A. Usually. Uh-huh.

Q. And you try to find out about the background and qualifications of the compliance officer?

A. Yes. Uh-huh.

Q. And you try to get a sense of how well they understand compliance principles?

A. Yes. Uh-huh.

Q. Do you have a sense of what Julie Kane's background was before she served in this role?

A. Yes, I did. I'm not sure that I can recall it at this point. I remember that she

see anything in the documents or the materials that indicated to whom she raised that, whether she raised that with Mr. Gorsky or someone else, maybe somebody in Sales. I didn't see anything in the materials indicating to whom she raised that.

Q. Okay. In the next sentence of your report, it says, "Under Ms. Kane's supervision, speaker programs were approved at questionable venues such as casinos and resorts."

And you cite to an instance where Mr. Putenis approved the use of a restaurant at a casino.

Do you recall Mr. Putenis' rationale for approving the restaurant at the casino?

A. No, I don't recall -- I don't recall his rationale about approving a restaurant at a casino.

Q. Do you recall his testimony that the reason he approved it was because it was during -- it was after Hurricane Katrina and there was a shortage of available restaurants to do these events in?

A. I have some vague recollection of

that, yes.

Q. Okay. And does that testimony impact your view on whether it was an appropriate choice of a restaurant given those circumstances?

A. It really does not affect -- it would not affect my opinion one way or the other, frankly.

Q. Meaning that, in your mind, it would still be inappropriate to hold a speaker program event at a restaurant within a casino?

A. Yes. Uh-huh.

Q. And why is that?

A. Because there were other venues that were available. I -- I'm familiar with the New Orleans area, and I don't believe that the casino was the only place that could have been used to house a speaker meeting or to have a speaker meeting.

Q. Okay.

A. So, I mean, maybe in this one circumstance he's making an exception, but my observation of Mr. Putenis is that there were a number of exceptions that he -- he would raise

and really defer to Sales as to whether or not it was an appropriate location.

Q. Uh-huh. At the end of the paragraph in your report, you wrote, "She believed," and this is Ms. Kane, "She believed that there were 'better ways to manage the risk' than a blanket prohibition on high-end restaurants, but she did not implement any."

A. Right.

Q. And if we could look at pages of the testimony, which is actually around the -- what you cite for -- in 135, page 223.

A. Okay, 223.

Q. It's actually -- it starts at the beginning of 222, and I can read it.

A. Okay.

Q. It says at line 22, "So, again, I think what we realized upon revisiting is that it wasn't so much whether or not the event was occurring at a Morton's or at a Ruth's Chris," which is the point you made in your report, correct?

MS. JUDE: Objection to form.

Q. That I --

A. That's what she said.

Q. Right.

A. She said that she thought there were better ways to manage the risk than a prohibition on high-end restaurants.

Q. Right. And then she continues, "It was whether we had sufficient and adequate controls around the events," and that's the next point you made is that she said there were better ways to manage the risk, correct? That's consistent with all of what you have said?

MS. JUDE: Objection to form.

A. That is what she said, yes.

Q. Right, what your description of what she said?

A. Yes.

Q. And then you say, "But she did not implement any better ways," and but what she says at line 6 is, "And so, for example, I think at some point we realized the better control might be enhancements to the programs in general, like having a third party help us manage them so that going into a meeting we might have a fixed menu, even if it was at a

documents that were referred to, I got those documents, and from those I tried to find other documents.

So that's what I looked at.

Q. And then you tried to weave all of the different sources of information together to explain to the reader what you saw happening during this period?

A. Yes, I think that's accurate.

Q. Let's look at page 57.

A. Uh-huh.

Q. The third paragraph on the page.

A. Okay. An example, uh-huh.

Q. No, the third paragraph. Sorry, the bottom paragraph. "Instead."

A. "Instead."

Q. It's where you're talking about an exception report.

So what is an exception report?

A. As I understand it, an exception report was a report that was run using Concerto data and NEC data to show instances where programs, speaker programs, were non-compliant, and those reports were run through Concerto and

then they were provided to the compliance officer or other folks in the Compliance Department, not necessarily Ms. Kane.

Q. Is the exception report an industry term or something that you saw for the first time with Novartis documents?

A. The first time I ever saw that phrase in my experience was this particular case, so...

Q. Okay. And you say, three lines from the bottom, "Exception reporting was not a regular process assigned to the Compliance Department."

Do you see that?

A. Yes.

Q. Do you recall the testimony of David Hollasch, who said that Beth Margerison was in charge of exception reporting?

A. Yes, I do remember him saying that she would -- that Ms. Margerison would pull reports from Concerto and provide them to the Compliance Department for further auditing or investigation. I remember him saying that.

Q. Right. So what do you mean when you say that exception reporting was not a regular

process assigned to the Compliance Department?

A. Well, it was my understanding based on Ms. Margerison's testimony as well as Ms. Cetani and Mr. Hollasch that the exception reporting was not something that was done on a regular basis, that there wasn't an exception report run every month or every quarter to show how far off they were in -- they were in terms of spending.

They had to run the reports, I guess, for certain states. So that's what Concerto was being used for, but exception reporting was something that was done on a more sporadic basis.

Q. So are you saying that the controls around exception reports were ineffective because exception reports weren't done on a regular enough basis?

A. Well, I think once that they had the opportunity to gather that information, NPC could have and should have set up an exception reporting process whereby, on a regular basis, the exception reports were brought to the attention of the compliance officer. The compliance officer then, perhaps, or someone at

his or her direction or even an outside investigator or auditor could take a look at what was causing -- what was the root cause for there being so many instances of policy violations, especially with respect to the modest meal policies and other attendance policies and things like that. That didn't appear to be happening.

Q. And did the failure to do so render this control ineffective?

A. I think, in part, it diminished its effectiveness, yes.

Q. To the point of ineffective?

MS. JUDE: Objection to form.

A. Well, I'm not sure you could really call it a control if it was -- not to quibble, but it was something that they were looking at, but they weren't effectively dealing with it until I think 2010 or so.

Q. Do you know whether other companies during the review period were doing exception reporting?

A. I do not.

Q. Let's look at the next page, 58.

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A. Okay.

Q. You say on the first full paragraph, "In my opinion, Compliance should have used Concerto and its predecessor systems to data-mine much earlier in the Review Period, and should have used it more broadly."

Do you see that?

A. Yes.

Q. And you felt that Novartis' compliance program would have been stronger if it had done more data analysis, correct?

A. Not -- yes, not only data analysis, but taking the information in the data and, as I testified earlier, folding that back into or incorporating it back into their compliance program in the form of additional audits, drilling down on particular audit areas, setting up a monitoring program, engaging in education, things of that nature.

So, you know, if you know that a particular geographic region is having a difficult time staying in compliance with policies and procedures, maybe what you do is you target specific training to that geographic

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region or that pod and then test them again in two or three months after the training and seeing -- to see where they are in terms of compliance at that point.

And that just -- they didn't seem to use any of that information, except with respect to honoraria and the aggregate spend on the physicians. That was really how Concerto was used, but it could have been used on a much broader scale.

Q. So, like in footnote 330, you recognize that Ms. Cetani noted that it was used for gift tracking, tracking specialties of the event attendees, venues and number of attendees, correct?

A. Right.

Q. But you thought there were other things that could have been tracked at that time?

A. Attendance I think would have been one thing to track. Meal spend would have been another one. So I just -- and they could have used it earlier. They had the capability to use Concerto from about 2007 onward, but they also

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had other systems like NEC and Report Central that could have been used to generate data that would have done the same thing, and they just -- there wasn't any organized effort on the part of the Compliance Department to collect and use the information in that way, which would have actually been a big help to them. It would have streamlined their efforts and helped them spend in the right direction, and it just didn't seem to be doing that.

Q. And you don't know whether other pharma companies during the review period were doing that sort of data analysis, do you?

A. I know some were.

Q. And how do you know that?

A. From my general experience, so...

Q. What does that mean, "general experience"?

A. From my experience working for Daylight, KPMG, looking at other compliance programs, reading cases.

Q. But specifically with pharma companies doing not just the sort of tracking that Ms. Cetani said was done, but the additional

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tracking that you say should have been done --

MS. JUDE: Objection to form.

Q. -- do you know with that level of granularity?

MS. JUDE: Objection to form.

A. I do not.

Q. Do you draw any conclusion about Novartis' -- let me start again.

Based on the fact that Novartis didn't do these things, like data analysis that you say they should have, do you draw any conclusion about Novartis' intent to comply?

MS. JUDE: Objection to the extent that it calls for a legal conclusion.

A. No, and I was not asked to make -- to determine intent, and I wouldn't really feel comfortable doing that, so...

Q. How about whether Novartis was acting in good faith to put in place an effective compliance program?

MS. JUDE: Same objection.

A. Once again, I didn't focus on issues of good faith. I just looked at the compliance program and tried to determine whether or not,

now if you've got a thousand employees, you need three people in your Compliance Department. I just don't know.

Q. But those benchmarks do exist?

A. I believe that they do. I haven't seen them.

Q. And do they -- when you say you haven't seen them, that's not something that you use when you review compliance programs?

A. No.

Q. But wouldn't that be helpful to determine, you know, a given company if they have 100 people that work in Compliance, you know, that's pretty good if the benchmark is only 30, say?

A. Well, I think it depends on how big the company is. I think it depends on the culture. I think it depends on how strong their policies and procedures are.

You may not need 50 inside compliance people if you've got a strong compliance officer and a system that works and you've got other methods of keeping the company in compliance, like a robust auditing and monitoring program,

you know, maybe you outsource it. I don't know, so it really depends.

Q. Sitting here today, you don't know how Novartis during this period measured up against those benchmarks?

A. No, I don't.

Q. Let's look at page 64.

A. Okay.

Q. You say, "Not surprisingly" -- this is on the fifth line. "Not surprisingly, given the staffing, NPC conducted a small number of investigations in speaker programs -- speaker program-related compliance violations relative to the total number of programs it conducted during the review period."

Do you see that?

A. Yes.

Q. Did you identify both the number of investigations of speaker program related compliance violations that NPC conducted as well as the total number of programs that it conducted during the review period?

A. I used the report of Mr. Goldberg, the other government expert, to come up with the

number of programs. I then went back and looked at some reports that Ann Harmon had put together trying to determine whether or not the program -- I think she actually used the words "had teeth" or how effective it was back during the October 2004 through March 2005 time period, and I was pretty surprised at how few speaker program investigations, compliance-related investigations had occurred given the other information in the documents about what the apparent risks were.

Q. Do you recall what the numbers of investigations were and what the total number of programs were?

A. I don't. I really don't. I would have to go back and look at the documents.

Q. And how were you able to determine that it was a small number?

A. Well, because there were thousands of speaker programs, and the number that were investigated during the time period were looked at -- the time period that was looked at by Ms. Harmon was really small, so...

Q. And do you -- do you have any

benchmarks of what other companies were doing as far as number of investigations to total number of speaker programs?

A. No, I don't.

Q. On the next page, you talk about the lack of proactive investigations. Do you see that?

The top of the page. It says, "And the Compliance Department" --

A. Oh, yeah.

Q. -- "largely refused to proactively investigate potential misconduct, instead waiting for an HPC or NPC employee to report misconduct."

Do you see that?

A. Yes.

Q. And at the last sentence, you wrote, "This hobbled Compliance's ability to prevent and detect misconduct."

Is there any guidance from OIG or otherwise about doing investigations in the absence of reported misconduct?

MS. JUDE: Objection to form.

A. I believe that the 2003 guidance talks